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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,089	06/09/2000	John C. Ford	8064.002US0	2891

7590 12/19/2002

COUDERT BROTHERS
600 BEACH STREET
SAN FRANCISCO, CA 94109

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/591,089

Applicant(s)

FORD, JOHN C.

Examiner

Brian Szmal

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franck et al and Hardy et al in view Front et al.

Franck et al discloses a body mounted sensing system for stereotactic surgery and further discloses a body fixed coordinate system; a reference point detecting means; a referencing means for determining the position of the seed; a real time seed position determining means; markers affixed to selected parts of the body; memory means for storing earlier obtained patient anatomical data; a coordinate transforming means for identifying the body fixed coordinate system with reference to the earlier obtained patient anatomical data; a real time visual display of the needle with reference to the body fixed coordinate system; a display for displaying the real time data; a real time display of the patient data; and updating the earlier obtained patient data. See Abstract; Column 5, lines 44-67; Column 6; Column 7, lines 1-53; Column 16, lines 5-19; and Figures 24b and 26.

Hardy et al discloses a three-dimensional simulation and computerized numerical optimization for dose delivery and treatment planning and further discloses the use of a dose calculating means for calculating in real time a radiation dose distribution within the selected volume; calculating a hypothetical radiation dose; and comparing the

calculated radiation dose and a predetermined distribution plan to determine the placement of the next seed. See Column 6, lines 29-33; Column 7, lines 31-68; Column 8, lines 1-23, 48-66; and Column 12, lines 58-66.

Franck et al and Hardy et al however fail to disclose the use of an injection device having a hollow injection needle for depositing seeds; an energy transmitting means attached to the needle; a detector at a fixed position with respect to a fixed space coordinate system; and means for determining the position and orientation of the needle.

Front et al discloses a method and system for guiding a therapeutic instrument towards a target region inside a patient's body and further discloses a hollow injection needle for depositing seeds; an energy transmitting means attached to the needle; a detector at a fixed position with respect to a fixed space coordinate system; and means for determining the position and orientation of the needle. See Column 6, lines 19-67; and Column 7, lines 26-41.

Since Franck et al, Hardy et al and Front et al disclose means for stereotactic brachytherapy surgery, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Franck et al and Hardy et al to include the disclosure of an injection needle and means for locating it in vivo, as per the teachings of Front et al, since it is well known in the art that a needle is used to deliver brachytherapy seeds as well as a catheter during seed implantation.

Response to Arguments

3. Applicant's arguments filed October 15, 2002 have been fully considered but they are not persuasive. The arguments relating to Franck's deficiencies are respectfully traversed. One of ordinary skill in the art would recognize the fact that when the system is used by the surgeon in the operating room, as shown in Figure 26, the system would be used in "real-time". Nowhere in the disclosure is it stated that the system records the current positions for future playback when the surgical procedure is performed. Figure 26 explicitly shows the setup of the system with the surgeon operating the command inputs (2620) and the feedback (2621). If the surgeon is applying inputs during a procedure and receiving feedback, it is in "real-time".

Franck discloses determining the position of the seeds during implantation, as stated in Column 16, lines 5-19, as an alternative embodiment. Using the drive mechanism of Franck, which determines the target location within the body using a body-fixed coordinate system, the implantation of brachytherapy seeds can be performed. Since it is well known in the art when brachytherapy seeds are implanted into soft tissue, such as brain tissue or in or around the prostate, the seeds do not migrate far from the distal end of the delivery device, whether it is a needle, a catheter or other delivery tube. The seeds rarely go farther than the actual opening of the insertion device. Since Franck discloses the means for locating the distal end of the device inside the body, the location of the seeds can be easily determined.

Franck further discloses the use of a body fixed coordinate system. See Figures 12 and 24b. The coordinate system comprises a system of fixed bone anchors, which provide means of fixed reference points on the skull. The Applicant argues that the

camera array, of Franck would not provide a means of detecting an insertion needle. The camera array of Franck is only a part of the entire system for tracking the position of instrument relative to the target location. The camera array is not the fixed coordinate system, as alluded to by the Applicant. The fixed coordinate system is physically affixed to the skull, hence a body-fixed coordinate system. The coordinate system works in conjunction with the signals from the sensors affixed to the probe to relay the exact position of the device within the body. See Figure 26, elements 2420, 2430 and 2610.

The Applicant argues, "Hardy was cited evidently for disclosing a three-dimensional simulation and computerized optimization system." Hardy was not "evidently" cited for the above element, it was cited because Hardy fully disclosed the above element.

Front et al, as well as Franck, disclose means for determining the position of the distal end of the probe member inside the body. As discussed above, the position of the deposited seeds can easily be determined simply by knowing the position of the distal end of the inserted device.

4. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Franck discloses

a means for stereotactic brain surgery, Front et al disclose a means for guiding a diagnostic or therapeutic element towards a target location, and Hardy et al disclose a means for dose optimization and therapy treatment planning for brain radiotherapy, including brachytherapy. Franck and Hardy et al were combined due to the fact they both disclose radiation treatment of the brain. The combination of Franck and Hardy et al along with Front et al is proper since Franck, Front et al and Hardy et al determine the position of the inserted probe within the body, regardless of the location of the probe on the body. Front et al discloses specific parts of the inserted probe that Franck and Hardy et al fail to disclose. The probe of Front et al is mainly for abdominal surgery, but one of ordinary skill in the art could adapt the elements of the probe to be used on any part of the body, and further use it in stereotactic surgery.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.



BS
December 18, 2002



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700